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| 10/825,930 | 04/16/2004 | Robert S. Neuwirth | ABL-101 | 9014 |

7590 01/25/2007
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| EXAMINER |
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ARNOLD, ERNST V

| ART UNIT | PAPER NUMBER |
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1616

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 01/25/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/825,930

Applicant(s)

NEUWIRTH, ROBERT S.

Examiner

Ernst V. Arnold

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-30 and 37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-30 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-13 and 31-36 have been cancelled. Claims 14-30 and 37 are pending.

The Examiner has a new ground of rejection and is therefore withdrawing finality and reopening prosecution. This action is non-final.

Comment: Claims 14, 15, 16, 19 and 27 recite "...tissue necrosing amount..."
The specification defines the term "necrosis" and grammatical variations thereof to mean death of cells in a tissue.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19, 20, 24, 25, 26, 28, 30 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsukisaka et al. (JP 05345010A).

The English language Abstract DERWENT-ACC-NO: 1994-039723 abstracting JP 05345010A and the machine translation have been provided for Applicant's benefit. The Abstract discloses a porous antibiotic bead with binder. The porous antibiotic bead with binder can be used in sanitary goods, which the Examiner interprets to mean that the beads are suitable for physiological use ([0001]). The bead can contain a water-soluble salt of an antibiotic metal (silver), such as silver nitrate (a water soluble inorganic salt) ([0013] and [0014]). Styrene beads and polyethylene beads can be used

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(instant claim 37). The Examiner interprets perforated polystyrene beads of instant claim 6 to mean porous. The metal is present from 0.01-10 w/w% and the average particle size might be 0.1-10 mm (5 mm is disclosed) and bead size can be easily regulated (Abstract and [0045]). The binder is distributed on the surface of the bead and represented physiologically tolerable alginic acid, carboxymethyl cellulose (CMC), polystyrene sulphonate, polyacrylate, etc..., thus reading on instant claims 24-26, 28 and 30.

It is the position of the Examiner that some silver nitrate will be on the surface of the bead. Given the broadest most reasonable interpretation, the presence of undiluted silver nitrate on the surface of the beads reads on instant claims 19 and 20.

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

Response to arguments:

Applicant asserted that the beads of Tsukisaka et al. are composite beads and not discrete individual beads. It is the Examiner's position that the claim language does not preclude composite beads.

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Applicant asserted that the beads of Tsukisaka et al. could be made water soluble to speed up dissolution of the silver ions and this would be undesirable for application in the uterus where the number of beads extracted from the uterus would be counted. It is the Examiner's position that the claim language does not preclude beads that dissolve in water.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 14-30 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsukisaka et al. (JP 05345010A) in view of Neuwirth (WO 96/40171) and Block (Disinfection, Sterilization and Preservation 1977, pages 395-407) and Hirai et al. (US 5,213,895) and Siiman et al. (US 5,552,086).

The Examiner is relying on the English language Abstract DERWENT-ACC-NO: 1994-039723 abstracting JP 05345010A and the machine translation which have been provided for Applicant's benefit in the prior Office Action.

Applicant claims a delivery vehicle for a silver ion releasing compound for use in the treatment of menorrhagia and comprising a plurality of separate physiologically inert beads bearing a tissue necrosing amount of a water soluble silver ion releasing compound coated on the surface of each bead, the bead having an average diameter in the range of about 1 to about 6 mm.

Determination of the scope and content of the prior art
(MPEP 2141.01)

The English language Abstract DERWENT-ACC-NO: 1994-039723 abstracting JP 05345010A and the machine translation have been provided for Applicant's benefit. The Abstract discloses a porous antibiotic bead with binder. The porous antibiotic bead with binder can be used in sanitary goods, which the Examiner interprets to mean that the beads are suitable for physiological use ([0001]). Tsukisaka et al. teach that the bead can contain a water-soluble salt of an antibiotic metal (silver), such as silver nitrate (a water soluble inorganic salt) ([0013] and [0014]). Tsukisaka et al. teach that styrene beads and polyethylene beads can be used. The Examiner interprets perforated polystyrene beads of instant claim 6 to mean porous. Tsukisaka et al. teach that the metal is present from 0.01-10 w/w% and the average particle size might be 0.1-10 mm (5 mm is disclosed) and bead size can be easily regulated (Abstract and [0045]). Tsukisaka et al. teach that the binder is distributed on the surface of the bead and

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represented physiologically tolerable alginic acid, carboxymethyl cellulose (CMC), polystyrene sulphonate, polyacrylate, etc...(Abstract).

Neuwirth teaches a composition for treating the endometrium of a uterus comprising 10% to about 50% by weight caustic agent (Claim 3). Neuwirth teaches that the caustic agent can be silver nitrate, silver thiocyanate or other compounds which can release silver ions thus establishing the equivalency of these compounds (Page 15, lines 6-9).

Block teaches that a fused composition can be prepared from silver nitrate, hydrochloric acid, salt and potassium nitrate and cast in molds (Page 396, toughened silver nitrate). It consists of 97-98% silver nitrate and the remainder is silver chloride. The intended use is for the cauterization of wounds and the removal of warts by application with a pencil.

Hirai et al. teach a particle-bearing composite comprising a solid carrier and polymer-protected particles adsorbed thereon (Abstract and column 5, lines 58-62). The solid carrier is preferable porous and made from organic polymers such as polystyrene and have a size of from about 1 micron to about 10 mm, but with no particular limitations, with a spherical or elongated shape (Column 5, lines 35-44 and column 6, lines 1-3 and 29-31). The Examiner interprets this to read upon beads. Hirai et al. teach a silver particle-polystyrene resin composite bearing 81×10^{-7} mole (as silver atoms) per gram of the polystyrene resin (Column 18, lines 5-9). The Examiner calculates this to represent about 0.87 mg of silver per gram of resin. The resin was made by adding a silver particle dispersion consisting of silver nitrate and poly(N-vinyl-2-pyrrolidone) to a

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macroporous polystyrene resin and thereby adsorbing the silver particles onto the polystyrene resin (Column 17, Example 15). It is the Examiner's position that the macroporous beads would inherently have at least a portion of the silver within the beads and thus read on instant claim 9. Poly(N-vinyl-2-pyrrolidone) acts a physiologically tolerable binding matrix.

Siiman et al. teach silver coated polystyrene beads (Abstract; and column 8, lines 10-18). Siiman et al. disclose that aminodextran coated polystyrene beads were added to a hot aqueous silver nitrate solution with stirring to ultimately form a uniform coating on the beads (Column 12, example 6-column 13, line 28).

**Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)**

1. Tsukisaka et al. do not expressly teach silver perchlorate, silver permanganate, silver acetate or silver lactate monohydrate as the silver ion-releasing compound.

2. Tsukisaka et al. do not expressly teach a delivery vehicle with up to about 5 percent by weight potassium nitrate.

3. Tsukisaka et al. do not expressly teach a delivery vehicle with about 20 to about 150 mg of silver nitrate or the narrower range of 50 to about 150 mg of silver nitrate.

4. Tsukisaka et al. do not expressly teach a delivery vehicle for a silver ion releasing compound wherein the polysaccharide is a dextran.

5. Tsukisaka et al. do not expressly teach a delivery vehicle for a silver ion releasing compound wherein the synthetic polymer is polyvinylpyrrolidone.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use silver perchlorate, silver permanganate, silver acetate or silver lactate monohydrate as the silver ion-releasing compound on the beads of Tsukisaka et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Neuwirth teaches equivalence of all silver compounds that release silver ions.

2. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the bead of Tsukisaka et al. with up to about 5 percent by weight potassium nitrate and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Bock teaches that potassium nitrate is an adjuvant for silver nitrate compositions.

3. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the bead of Tsukisaka et al. with about 20 to about 150 mg of silver nitrate or the narrower range of 50 to about 150 mg of silver nitrate and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the loading of more antimicrobial material, silver nitrate, on the bead would result in the

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presence of more silver ion for antimicrobial activity and is merely a matter of routine optimization for one of ordinary skill in the art.

4. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the bead of Tsukisaka et al. with a binding matrix wherein the polysaccharide binding matrix is a dextran and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Siiman et al. teaches making silver coated beads with a dextran and Tsukisaka et al. teach cellulose which renders other polysaccharides such as dextran obvious to one of ordinary skill in the art.

5. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the bead of Tsukisaka et al. wherein the synthetic polymer is polyvinylpyrrolidone and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Hirai et al. teaches compositions where the addition of polyvinylpyrrolidone is common in making a resin made by adding a silver particle dispersion consisting of silver nitrate and poly(N-vinyl-2-pyrrolidone) to a macroporous polystyrene resin.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

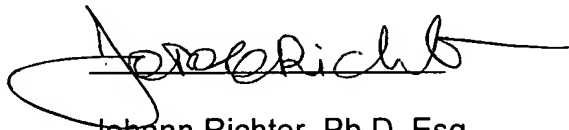
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst Arnold
Patent Examiner
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Art Unit 1616

A handwritten signature in black ink, appearing to read 'Johann Richter', with a large, sweeping loop on the left side.

Johann Richter, Ph.D. Esq.
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